MAR 1 1 2004

2. 510(k) SUMMARY of Safety and Effectiveness

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

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2.2 Contact Person: [807.92 (a)(1)]

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2.3 Date Summary Prepared: [807.92 (a)(1)]

September 24, 2003

2.4 Device Names: [807.92 (a)(2)]

Proprietary **POWER**GRIP Coagulation Forceps
Common Coagulation Forceps

Classification Name	**Prod. Code**	**CFR**
Laparoscope, Gynecologic (& Accessories)	85 HET	CFR 884.1720
Unit, Electrosurgical, Endoscopic, (with/without Accessories)	78 KNS	CFR 876.4300

2.5 Reason for Submission:

Change in control mechanism of forceps jaws

2.6 Modification to Existing Device: [807.92 (a)(3)]

K 970968 Bissinger Detachable Bipolar Coagulation Forceps (Cleared 05/21/98)

2.7 Device Description: [807.92(a)(4)+(6)]

The POWERGRIP coagulation forceps are designed for grasping, cutting and bipolar coagulation in minimally invasive surgery.

The POWERGRIP handle actuates the jaws of the electrode inserts by means of a double-hinge and serves as the point of attachment for accessories (shafts, inserts, cables).

2.8 Reasons for Device Modification: [807.92 (d)]

Control Mechanism Change:

1. To improve handling control with respect to direction and accuracy of forceps during surgical procedures;
2. To make disassembly and re-assembly easier, faster and more effective for exchange of electrode jaws during procedure and for reprocessing.

2.9 Intended Use: [807.92 (a)(5)]

Bipolar tissue coagulation in gynecologic and laparoscopic surgical procedures.

2.10 System Components

The system consists of the following elements:

POWERGRIP Bipolar Coagulation Forceps		Detachable Bipolar Coagulation Forceps K 970968
Powergrip Handle		SE
Exterior Tube (Shaft, various lengths)		SE
		Interior Tube (various lengths)
Electrodes	Grasping Forceps (large, small, Micro France) (various types & sizes)	SE
"	Preparation Forceps (various types & sizes)	SE
"	Scissors Forceps	SE
"	Dissecting Forceps (i.e. Maryland)	SE
Cables[1]		SE

[1] K 981919 Bipolar Cables (GEI, Class II, CFR 878.4400), cleared 06/08/98

2.11 Industry Standards: [807.92 (d)]

BISSINGER certifies compliance with all appropriate industry standards and the validation of methods and processes covered by these standards.

2.12 MRI Environment: [807.92 (d)]

Not applicable

2.13 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The Bissinger **POWER**GRIP Bipolar Coagulation Forceps have the same intended use as the previously cleared devices. There is no change in materials, classification or labeling. There is also no change in how the surgeon controls the device. The only change is the internal activation of the jaw movement.

THIS CHANGE DOES NOT AFFECT THE SAFETY OR EFFECTIVENESS OF THE DEVICE. Rather, the internal mechanical connection to the jaws improves the surgeon's control of the electrode jaws and assures well adjustable opening and closing of the jaws with very high pressure during grasping and cutting and high precision in tissue coagulation.

Like the predicate device, effective cleaning and sterilization are assured due to a built-in mechanism that keeps forceps jaws open during reprocessing.

There are no additional characteristics known that should adversely affect the safety and effectiveness of these devices.

The results of design validation raise no new issues of safety and effectiveness.

2.14 COMPARISON of DESIGN + SAFETY and EFFECTIVENESS

Device	POWERGRIP Bipolar Coagulation Forceps	Detachable Bipolar CoagulationForceps
Catalog #	824 xxxxx	855 xxxxx
Intended Use	Bipolar tissue coagulation in gynecologic and laparoscopic surgical procedures	**Identical**
Length -	200, 250, 340, 450 mm	**200, 340, 450 mm**
Materials	PEEK, PTFE, Stainless Steels 301, 303, 304, 420, Silicone	**Identical**
Forceps Styles	Grasping jaws, small & curved scissors, Micro France, preparation forceps	**Substantially Equivalent**

Design Comparison	Bissinger Powergrip Bipolar Coagulation Forceps are designed to provide concentrated cutting force with surgeon's hand control. Compressing the handle, closes electrode jaws and gently releasing it, opens them. Jaw position can be changed 360° by moving small wheel at handle with index finger and locks into place during surgical procedure, reducing hand discomfort/fatigue. The device is designed for right and left-hand operation. The overall design is substantially equivalent to previously cleared and competitive devices.	The Bissinger Detachable Bipolar Coagulation Forceps are designed to provide concentrated cutting force with surgeon's hand control. Compressing the handle, moves an inner tube forward to close the jaws. The tube recedes when compression is released to open them again. The position of the jaws is regulated by turning a wheel at the top rear of the handle. An internal locking mechanism assures that position during surgical procedure and reduces hand discomfort/fatigue. The instrument is designed for both right and left hand use.
Safety & Effectiveness of Operating Principle Change [807.92 (b)(1)]	The change in jaw activation improves the surgeon's control over the closing and opening action of the bipolar jaws. The indications for use, materials, and general operating instructions remain identical. The different inserts can be exchanged in seconds during surgical procedures. The POWERGRIP dismantles into three parts for thorough and reliable reprocessing and to facilitate repairs/replacement of defective parts. The device modification introduces no new risk for patient or surgeon and enhances device safety and effectiveness when compared to the predicate. *Careful attention must be paid to Bissinger's user instructrions.*	

Signature: _____ Date: September 26, 2003

Matthias Bissinger
Director, Product Development
& Production

Insulation & Insulation Material	PTFE, jaws are insulated up to the end of the grasping or cutting zone to avoid inadvertent coagulation	**Substantially Equivalent**
Control of jaw position	360° rotation of electrode insert by moving star-shaped wheel with index finger; jaw position remains stable with opening and closing to ensure precise work when dissecting, cutting, grasping and coagulating.	**Substantially Equivalent**
Sterile	No	**No**
Design Comparison	The Bissinger Powergrip Bipolar Coagulation Forceps is designed to provide concentrated/cutting force with surgeon's hand control. Compressing the handle, closes electrode jaws and gently releasing it, opens them. Jaw position can be changed 360° by moving small wheel at handle with index finger and locks into place during surgical procedure. This reduces hand discomfort/fatigue. The device is designed for right and left-hand operation. The overall design is substantially equivalent to previously cleared and competitive devices.	The Bissinger Detachable Bipolar Coagulation Forceps is designed to provide concentrated/cutting force with surgeon's hand control. Compressing the handle, moves an inner tube forward to close the jaws. The tube recedes when compression is released to open them again. The position of the jaws is regulated by turning a wheel at the top rear of the handle. An internal locking mechanism assures that position during surgical procedure and reduces hand discomfort/fatigue. The instrument is designed for both right and left hand use.
UL Compliant	UL-544	**Identical**
ISO Compliant	ISO 9001	**Identical**
Safety & Effectiveness of Operating Principle Change [807.92 (b)(1)]	The jaw activation change improves the surgeon's control over the closing and opening action of the bipolar jaws. The indications for use, materials, and general operating instructions remain identical. The design changes facilitate dis- and reassembly before and after reprocessing. The change introduces no new risk for patient or surgeon and rather enhances device safety and effectiveness when compared to the predicate. *Careful attention must be paid to Bissinger's user instructions.*	

Signature: _____ **Date:** September 26, 2003

Matthias Bissinger
Director, Product Development
& Production

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2004

Gunter Bissinger Medizintechnik GMBH
% Mr. Dagmar Masër
Official Correspondent
Business Support International
Amstel 320-I, 1017 AP, Amsterdam
THE NETHERLANDS

Re: K033177
Trade/Device Name: POWERGrip Bipolar Coagulation Forceps
Regulation Number: 21 CFR 884.1720
Regulation Name: Gyneclogical Laparoscope and Accessories
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: 85 HET and 78 KNS
Dated: February 5, 2004
Received: February 9, 2004

Dear Mr. Masër:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K033177

Device Name **POWERGRIP** Bipolar Coagulation Forceps

INDICATION FOR USE

Bipolar tissue coagulation in gynecologic and laparoscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033177

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Format 1-2-96)